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CONFIRMATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE 6911 10/629,511 07/29/2003 John C. Jeppesen **EXAMINER** 23871 06/23/2005 JOHN C JEPPESEN BUNIN, ANDREW M **8220 EDISON DRIVE** ART UNIT PAPER NUMBER VENTURA, CA 93001

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.                                       | Applicant(s)                        |
|---|---|-------------------------------------|
| Office Action Summary   | 10/629,511  | JEPPESEN, JOHN C.                   |
|   | Examiner  | Art Unit                            |
|   | Andrew M. Bunin                                       | 3743                                |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |                                     |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                     |
| Status  |   |                                     |
| 1) Responsive to communication(s) filed on  |   |                                     |
| 2a) This action is <b>FINAL</b> . 2b) This  | action is non-final.                                  |                                     |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |                                     |
| Disposition of Claims   |   |                                     |
| 4) Claim(s) 1-37 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to.  | vn from consideration.                                |                                     |
| 8) Claim(s) <u>1-37</u> are subject to restriction and/or election requirement.   |   |                                     |
| Application Papers  |   |                                     |
| 9) The specification is objected to by the Examiner.  |   |                                     |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |                                     |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                                     |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                                     |
| Priority under 35 U.S.C. § 119  |   |                                     |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |                                     |
| Attachment(s)   |   |                                     |
| 1) Notice of References Cited (PTO-892)   | . 4) Interview Summary                                |                                     |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date  | Paper No(s)/Mail Do 5) Notice of Informal P 6) Other: | ate<br>Patent Application (PTO-152) |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-10, drawn to a method for treating Obstructive Sleep Apnea
   Syndrome (OSAS) with positive airway pressure (PAP), classified in class
   128, subclass 848.
- II. Claims 11-17, drawn to a device, which obturates the oral cavity during treatment of OSAS, classified in class 128, subclass 848.
- III. Claims 18-32, drawn to method of applying PAP to nasal passages, classified in class 128, subclass 848.
- IV. Claims 33-37, drawn to a method of establishing the mandible in a certain position, classified in class 128, subclass 848.

Inventions of Groups I and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method for treating OSAS involves the aspect of retaining upper and lower dental arches in elastomeric material via a snap-fit which is not included in the claims pertaining to the device in Group II. Therefore, the device used to perform the method of Group I could be different from the device claimed in Group II.

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Inventions of Group I and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the device in Group I doesn't need or include the PAP system with a Variable Length Slide that is bonded to the anterior surface of oral appliance as well as some other particular aspects of the PAP system such as the thickness and positioning in relation to the labial surface. The subcombination has separate utility in that the PAP system can be separated from the mouthpiece section and be used on its own for ventilating a patient. In addition, the mouth guard or mouthpiece can function on its own in order to obturate the oral cavity.

Inventions of Group I and Group IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the device of Group IV can be separated from the combination in Group I for pushing the mandible in

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a certain position. The subcombination has separate utility in that a specific type of mouth guard may be placed in the users mouth in combination with an outside source of TENS or physical manipulation to stabilize the position. This can be accomplished with a device that doesn't include the PAP tubing process.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, or IV, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: Within Group II, claim 12 states a preferred position whereby the mandible is not protruded and is located in neutral and claim 14 states a preferred position whereby the mandible is located in an anterior protruded position.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic since it corresponds with the dual arch further described in claims 12 and 14.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: Within Group IV, claims 36 and 37 describe capturing a neutral centric position via Transcutaneous Electrical Nerve Stimulation (TENS) or via conventional techniques such as manual physical manipulation of the mandible.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic since it describes the use of the same dual arch appliance further in claims 36 and 37.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMB 6/09/05

> Henry Pennett Supervisor, Patent Examine